

statement of composition which appeared on the label was given in Latin rather than in the English language.

On February 5, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

995. Misbranding of Ekzebrol. U. S. v. 12 Boxes and 5 Boxes of Ekzebrol. Default decree of condemnation and destruction. (F. D. C. No. 9138. Sample No. 14703-F.)

On January 5, 1943, the United States attorney for the Southern District of California filed a libel against 12 boxes, containing 6 ampuls each, and 5 boxes, containing 25 ampuls each, of Ekzebrol at Los Angeles, Calif., alleging that the article had been shipped in interstate commerce on or about October 23, 1942, by E. Tosse and Co. from Brooklyn, N. Y.; and charging that it was misbranded. The article was labeled in part: "Ekzebrol 10% Strontium Bromide in Sterile Saline Solution For Intravenous Injection."

The article was alleged to be misbranded in that the following statements appearing on the circular contained within the package: "Bromine has been given orally with success in support of external treatment of some forms of eczema, particularly those caused by nervous conditions. It has, however, been demonstrated that by parenteral injection its soothing influence is augmented and quickened to such an extent, that especially in acute cases, this treatment alone will suffice. In Ekzebrol, bromine is combined with strontium, the former acting on the nerve centers, the latter on the peripheral nerves. Strontium probably exerts also a vascular constricting effect," and "In Skin diseases caused by an abundance of chlorides, the chlorides become free after a bromine injection and are eliminated in a natural way," were false and misleading since strontium bromide when administered by parenteral injection does not have its soothing influence so augmented that it alone will be effective for acute cases of eczema; strontium bromide does not act on the nerve centers and peripheral nerves, and does not have a vascular constricting effect; and Ekzebrol will not be effective in the skin diseases caused by an abundance of chlorides.

On February 24, 1943, no claimant having appeared, judgment of condemnation was entered and the product was ordered destroyed.

996. Misbranding of double strength solution of posterior pituitary. U. S. v. 1 Litre and 2 Bottles of Double Strength Solution of Posterior Pituitary. One lot tried to the court. Decrees of condemnation and destruction. (F. D. C. Nos. 7807, 7815. Sample Nos. 89506-E, 89507-E.)

On June 26 and 29, 1942, the United States attorneys for the Southern and Eastern Districts of New York filed libels against 1 litre, at Brooklyn, N. Y., and 2 bottles, each containing 1 litre, of double strength solution of posterior pituitary, at New York, N. Y., alleging that the article had been shipped on or about November 18, 1941, by Armour and Co., Chicago, Ill.; and charging that it was misbranded.

The article was alleged to be misbranded in that the statements on its label, "Double Strength Solution of Posterior [or "Post"] Pituitary U. S. P. XI," and "20 I. U. per cc." were false and misleading since the strength of the article was not double that of solution of posterior pituitary, as defined in the eleventh revision of the United States Pharmacopoeia, and was not 20 International Units per cc.

On February 5, 1943, Armour and Co. of Delaware, having appeared as claimant for the lot at New York and having denied the allegation in the libel with respect to misbranding and the case having come on for trial, the court, after hearing the evidence and the arguments of counsel, handed down the following memorandum opinion:

WILLIAM BONDY, District Judge: "Assuming that there was sufficient evidence of identity of the contents of the exhibits 1 and 3 in evidence, and of samples from which the tests were made by the claimant; and assuming that all the tests as to which evidence was given were properly made, as to which there is a very serious question, there is no proof that any of the tests disclosed more than 18.5 International Units. The Court believes that what might be called the tolerance of 20 percent either way was a tolerance allowed in determining whether the product complies with the requirements of the Food and Drug Act and whether it may be transported in interstate commerce. The Act does not authorize anyone to represent the strength of the solution in International Units in the absence of reasonable certainty on the part of the person making the representation.

"The label used by the claimant states specifically that the solution in the two bottles that were seized was 'Double Strength Solution Posterior Pituitary U. S. P. XI 20 I. U. per CC. For Manufacturing Use. Expiration date September 1943.'

"The Court understands that to be a representation that the solution had a strength of 20 International Units. The evidence of the experts on behalf of the government, whom the Court believes to be very well qualified, testified that it never was a double strength solution of 20 International Units, or, in other words, that it never exceeded at any time 16.2 Units. The claimant's experts, also men of unquestionable competence, testified that by the methods used by them in making their assays which they claim were used in compliance with the Pure Food and Drug Act, it at most equalled 18.5 Units.

"The only issue is whether the solution was properly labeled or branded. The evidence in the case shows that the solution never was a solution of 20 International Units.

"The Court is convinced that the claimant believed it was authorized to label the solution containing 18.5 as a 20 International Units solution, in view of the tolerance allowed by the Pharmacopoeia.

"The claimant was mistaken in believing that it was entitled to use that tolerance in making an absolute representation that the solution was one of 20 International Units.

"The label or representation was not correct. The two bottles were properly seized and must be condemned.

"There accordingly should be a decree in favor of the libellant, with costs."

On March 4, 1943, the court made the following findings of facts and conclusions of law:

WILLIAM BONDY, *District Judge*:

FINDINGS OF FACT

"1. That the two bottles, each containing one litre of an article labeled in part 'Double Strength Solution of Posterior Pituitary U. S. P. XI 20 I. U. per CC.' contained a solution of posterior pituitary the strength of which was not double the strength of solution of posterior pituitary U. S. P.

"2. That the two bottles described in finding No. 1 contained a solution of posterior pituitary which did not contain more than 18.2 International Units per cubic centimeter.

"3. That at no time since its manufacture by the claimant herein did the two bottles of solution of posterior pituitary herein contain 20 international units per cubic centimeter.

"4. The statement on the label of the product, 'Double Strength Solution of Posterior Pituitary, U. S. P. XI 20 I. U. per cc.' was false and misleading."

CONCLUSIONS OF LAW

"1. The product was misbranded while in interstate commerce.

"2. The product must be condemned."

On March 9, 1943, judgment of condemnation was entered against the lot at New York and it was ordered destroyed. On May 24, 1943, Pro-Medico Laboratories, Inc., Brooklyn, N. Y., claimant for the lot at Brooklyn, having filed an answer denying the allegation in the libel with respect to misbranding and subsequently having withdrawn its answer, judgment of condemnation was entered and the lot was ordered destroyed.

997. Misbranding of Thompson's Daily Vitamin and Mineral Ration. U. S. v. 8 Cartons of Thompson's Daily Vitamin and Mineral Ration. Consent decree of condemnation. Product ordered released under bond for relabeling. (F. D. C. No. 9040. Sample No. 13242-F.)

This product was represented in its labeling as supplying $1\frac{1}{4}$ times the minimum adult daily requirements of vitamins A and D, the minimum adult daily requirement of vitamin C and riboflavin, and 3 times the minimum adult daily requirement of vitamin B₁. It was also represented as containing specified amounts of vitamin B₆, niacin amide, pantothenic acid, and biotin, as well as calcium, phosphorus, iodine, iron, and copper.

On December 24, 1942, the United States attorney for the Western District of Washington filed a libel against 8 cartons, each containing 100 boxes, of the above named product at Seattle, Wash., alleging that the article had been shipped in interstate commerce on or about October 12, 15, and 20, 1942, from Los Angeles, Calif., by the William T. Thompson Co.; and charging that it was misbranded.